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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,949	01/16/2001	Masami Kohchi	20532	4774

151 7590 06/03/2003
HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,949

Applicant(s)

KOHCHI ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 10
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 1-13 are pending.

Applicants' amendment filed on April 1, 2003 (Paper No. 9) is acknowledged, and applicants' response has been fully considered. Claim 13 has been amended, and claims 1-13 are examined. During a conversation with Attorney, Lyman Smith on May 23 and 26, 2003, a proposed Examiner's amendment and a terminal disclaimer against U.S. Patent 6,489,440 were suggested (See Interview Summary), however, the applicant did not accept the proposal. Examiner found the structure of aerothricin shown in claim 1 of U. S. Patent 6,489,440 is not correct, and Attorney informed Examiner that the certificate of correction of the patent has been filed.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous of rejection of claim 13 under 35 U.S.C. 112, second paragraph is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 6-7 in Paper No. 9.

Claim Objections

3. Claim 13 is objected to because the claim has been amended, but it cites the bracket ([...]). Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. In claim 13, applicant has used "[...]" in R¹ in such a manner that appears that the instant brackets would indicate deleted material and is thus, confusing as to whether the

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description inside the bracket would be included or not. The applicant can only amend by cancellation and presentation of a new claim. See also changes to 37 CFR 1.121 in Amendment rules package (Final Rule published on 8 Sep. 2000 (65 Fed. Reg. 54603), see also O. G. of 19 Sep. 2000 (1238 Off. Gaz. Pat. Office 77)).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 7, 10-13, 18, 19, 26, 27, 30, 31, 46, 47, 50 and 51 of U. S. Patent 6,489,440. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 in the instant application discloses a compound of formula (I) with specific substituents of Aerothricins; and a pharmaceutical composition comprising the compound of formula (I) and a pharmaceutically acceptable carrier. This is an obvious variation in view of claims 1, 3, 4, 7, 10-13, 18, 19, 26, 27, 30, 31, 46, 47, 50 and 51 of the '440 patent, which discloses and claims aerothricins and a composition comprising compounds of aerothricins and a pharmaceutically acceptable carrier. Both the claims of instant application and the claims of the patent are directed to the compound of formula (I) with specific

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substituents of Aerothricins. Thus, claims 1-12 in present application and claims 1, 3, 4, 7, 10-13, 18, 19, 26, 27, 30, 31, 46, 47, 50 and 51 of the patent are obvious variations of a compound of formula (I) with specific substituents of Aerothricins, and a pharmaceutical composition comprising the compound of formula (I) and a pharmaceutically acceptable carrier.

5. Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10 and 27-32 of copending application No. 09/765,846 (US 2001/0038824 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 in the instant application discloses a compound of formula (I) such as Aerothricins 124, 132 and 134-137; and a pharmaceutical composition comprising the compound of formula (I) and a pharmaceutically acceptable carrier. This is obvious in view of claims 1, 10 and 27-32 of copending application which discloses a pharmaceutical composition comprising a physiologically active cyclic peptide such as Aerothricins 124 and 132-137 and a pharmaceutically acceptable particulate carrier such as particulated polyvalent metal carrier or a particulated organic carrier. Since both the claims of instant application and the claims of the copending application are directed to a pharmaceutical composition comprising the compound of formula (I) with specific substituents of Aerothricins. Thus, claims 1-12 in present application and claims 1, 10 and 27-32 of copending application are obvious variations of a compound of formula (I) such as Aerothricins 124, 132, 134-137, and a pharmaceutical composition comprising the compound of formula (I) and a pharmaceutically acceptable carrier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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In response, applicants indicate because the rejection is provisional double patenting rejection, applicants request withdrawal thereof should the claims be otherwise in condition for allowance. The comment is unpersuasive. The ground of rejection remains. No allowable material can be indicated when a ground of rejection remains.

Conclusion

6. Claims 1-12 are rejected, and claim 13 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

May 31, 2003

Christopher S. F. Low
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